II. REMARKS

A. Status of the Claims

Claims 1-35 are pending in the application. Claims 22-35 have been withdrawn from consideration as being drawn to a non-elected invention. Thus, claims 1-21 were examined in the Action. Claim 2 has been amended to independent form and claims 6 and 15 have been amended to depend from claim 2. Claim 22 was amended to incorporate the limitations of claim 23 and claim 24 was amended to depend from claim 22. Claims 1, 21, and 23 have been canceled. Thus, claims 2-20, 22, and 24-35 are currently pending and claims 2-20 are currently under examination.

B. Response to the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures

In response to the Notice to Comply that accompanied the Office Action, Applicants have amended the specification herein to include the appropriate sequence identifiers and to enter the substitute Sequence Listing. A substitute Sequence Listing for entry into the specification is attached hereto, and a substitute computer readable form (CRF) of the Sequence Listing and a statement that the content of the paper and CRF copies of the Sequence Listing are the same and include no new matter are submitted concurrently herewith.

C. The Rejection Under 35 U.S.C. § 101

The Action rejects claim 21 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Claim 21 has been canceled rendering this rejection moot.

D. The Claims Are Definite Under 35 U.S.C. § 112, Second Paragraph

The Action rejects claims 2-5, 7-14, and 21 under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the Action asserts that: (1) claims 2-5 are vague and indefinite because it is not clear what is meant by "downstream promoter element" or "upstream binding element;" (2) claims 2-5 are vague and indefinite because it is not clear to what the "upstream binding element" binds; (3) claims 2

and 21 are vague and indefinite because it is not clear what is being initiated by the "initiator;" and (4) claims 5-6 are vague and indefinite because it is not clear to which protein the acronym "CBP" refers. Applicants address each of these issues below.

1. "Initiator"

The Action asserts that it is not clear what is being initiated by the "initiator" in claims 2 and 21. Applicants traverse this rejection.

A proper evaluation under the second paragraph of 35 U.S.C. § 112 requires that the claim be read in light of the specification as interpreted by one of ordinary skill in the art. The term "initiator" is well known to those of ordinary skill in the art. As described in the specification, initiation elements are sequences recognized specifically by initiator-binding proteins (Specification, p. 13, ln. 6-7). Interaction between these initiator binding proteins and components of the basal transcription machinery provides a means through which a transcription competent complex can be formed and transcription can be initiated (Specification, p. 13, ln. 7 to p. 14, ln. 3). Thus, it would be clear to a person of ordinary skill in the art that transcription is what is being initiated by the initiator.

Furthermore, various initiators have been described and classified according to sequence homology. In an exemplary promoter construct disclosed in the specification, the initiator TCATTC described by Smale and Baltimore (1989) was placed at position +1 (Specification, p. 26, ln. 13-16). Example 7 in the specification describes studies in which the effect of moving the initiator closer or farther from the TATA box was studied.

2. "Downstream Promoter Element" and "Upstream Binding Element"

With regard to the rejection of claims 2-5, it appears that the Action is viewing "downstream" and "upstream" as describing a positional relationship of the downstream promoter element and upstream binding element to a gene operably linked to these elements. Thus, the Action concludes that claims 2-5 are indefinite because they do not recite such an operably linked gene. Applicants traverse this rejection.

As mentioned above, a proper evaluation under the second paragraph of 35 U.S.C. § 112 requires that the claim be read in light of the specification as interpreted by one of ordinary skill in the art. As

described in the specification at, for example, page 26, lines 10-19, a exemplary synthetic promoter construct was centered by a TATA box with the initiator at position +1 and with various binding sites and other elements added upstream and downstream of the TATA box. The "downstream promoter element" refers to a particular type of promoter element described by Burke *et al.* (*see e.g.,* Specification, Table 1, and p. 27, ln. 29), and which was named the downstream promoter element because it was first identified downstream of the RNA start site. Furthermore, in Example 8 of the specification the placement of downstream element is described relative to the initiator sequence (p. 31, ln. 9-21). Thus, the recitation of an operably linked gene is not necessary to understand the meaning of the term "downstream promoter element." Also as described in the specification, the tem "upstream binding element" refers to an element located upstream of the core promoter region, *i.e.,* the TATA box (Specification, p. 32, ln. 7-12). Examples of upstream binding elements provided in the specification include the IRF, SP1, CBP, NFκB, AP1, and IFN binding elements (Specification, p. 4, ln. 10-18; p. 32, ln. 9). Citations to publications describing these binding elements may be found in Table 1 of the specification. The Action's further assertion that an "upstream binding element" refers to a binding element to which "upstream" binds is unsupported by any reasoning and is inconsistent with the meaning of the this term to a person of ordinary skill in view of the disclosure in the specification.

3. "CBP Binding Element"

The Action asserts that claims 5-6 are vague and indefinite because it is not clear to which protein the acronym "CBP" refers. As indicated in the present specification, the CBP binding element refers to the CBP binding element reported by Graves *et al.* (*see e.g.,* Specification, Table 1). Thus, in view of the present specification, a person of ordinary skill in the art would understand that "CBP" denotes "CAT binding protein."

4. Conclusion

A proper evaluation of claims 2-5, 7-14, and 21 under the second paragraph of 35 U.S.C. § 112 requires that the claims be read in light of the specification as interpreted by one of ordinary skill in the art. For the reasons provided above, the terms "downstream promoter element," "upstream binding

element," "initiator," and "CBP binding protein" are definite, and claims 2-5, 7-14, and 21 satisfy all of the requirements under 35 U.S.C. § 112, second paragraph. Applicants, therefore, request the withdrawal of this rejection.

E. The Claims Are Novel and Patentable Over the Cited References

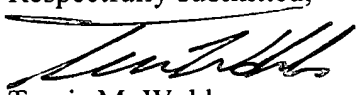
The Action raises various anticipation and obviousness rejections. Claim 2 was not rejected as being anticipated or obvious. Claim 2 has been amended to independent form and all of the other claims currently under examination depend either directly or indirectly from claim 2. Thus, the Action does not establish a *prima facie* case of anticipation or obviousness against the current claims. Applicants, therefore, request the withdrawal of these rejections.

F. Conclusion

Applicants believe that this paper is a full response to the Office Action dated April 14, 2006. Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicants' representative at (512) 536-5654.

Please date stamp and return the enclosed postcard evidencing receipt of this paper.

Respectfully submitted,



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Date: August 14, 2006